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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,510	03/30/2004	Stephen J. Petti	2098.003	3250

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,510	PETTI ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are presented for reconsideration on the merits.

Response to Amendment

The amendment filed September 25, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Also the extension of time filed therewith is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernd Elger et al, cited on enclosed PTO-1449 Form, in view of Schwartz et al (US 5523292), cited on enclosed PTO-892 Form.

Claims are drawn to a method for treating stroke in a patient by administering ancrod intravenously at varied time intervals and in effective amounts, therefore.

Elger et al teach a method for treating stroke in a patient by administering ancrod intravenously at varied time intervals and in effective amounts, therefore. Note page 895, summary section.

Schwartz et al teach a method for preventing restenosis by administering ancrod intravenously at varied time intervals and in effective amounts, therefore. Note col. 2, lines 54-67 and col. 3-4, lines 1-20. Also note col. 6, line 60.

The claims differ from Elger in that the specific time intervals and effective amounts are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat stroke with ancrod as disclosed by Elger by selecting for the time intervals and effective amounts which have proven efficient in preventing restenosis which is also related to the onset of stroke in a patient. Clearly with successful dosages and time intervals taught by Schawrtz one of skill would have expected successful results for treating stroke as ancrod is known to be effective but the amounts disclosed by Schwartz would have motivated one of skill to select and administer these amounts to a stroke patient as well for treatment therefore.

The identical effective range amounts are disclosed by Schwartz and for one of skill to glean what has already been performed in the art for one disease is clearly an obvious moficiation of the cited prior art. Each of the claim features are disclosed by Schwartz but he is not treating stroke per se. One of skill would have expected that the

amounts would work because the same identical compound is useful to treat stroke patients. Further, the amounts administered by Applicants' claimed methods are disclosed by Schawartz to be generally known in the art, note col. 2, lines 65-67. In the absence of persuasive evidence to the contrary the claims are prima facie obvious.

Response to Arguments

The argument that Applicants' specific defibrinogenation pattern achieves better results than disclosed in the prior is noted, however, the Elger reference clearly teaches that their method of administration achieves the same results, reduction in adverse side effects such as intracranial hemorrage, see page 898, column 2, last 5 to 6 lines. None of Elger's ancrod-treated animals showed adverse side effects such as intracranial hemorrhage. Ancrod is disclosed to be a safe treatment for stroke.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a normalization step to provide for *pretreatment fibrinogen levels* and treatment on a human patient) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, any arguments directed to a normalization step for providing basal levels and for treating humans is not deemed persuasive.

Further, the argument that Elger et al do not teach treating stroke is noted, however, the reference clearly teaches at page 898, as noted above, that ancrod is a safe treatment for stroke. The fact that the Elger reference teaches a research study for

treatment of stroke does not omit a teaching for stroke in a patient because the teaching clearly suggest, if not teaches, that ancrod is used for treating stroke and does teach administering ancrod to an animal (i.e. paitent) and the specific pattern of its administration is taught or at least suggested by Elger et al in combination with Schwartz et al.

In addition, the arguments directed to two references of which Applicants allege that they provided with their response in support of their arguments regarding use of animal models are noted. However, no such references were observed by the Examiner to be present in the instant application. Nonetheless, the points upon which Applicants address in their response regarding these references as support for their proposition that animal models need to be considered in context with respect to their limitations are acknowledged by the Examiner. However, as noted above these arguments are not persuasive since the claims do not require treatment of humans and because even if the claims were directed to humans such a reference which used animal modes would indeed suggest that the same method would be expected to provide successful results in humans, as well.

The arguments regarding Schwartz et al are noted and for reasons discussed above at least with respect to the arguments regarding animals are not deemed persuasive. However, the other point of argument raised by Applicants that Schwartz et al does not teach stroke is noted, but a narrowing of the blood vessel leads to stroke and hence ancrod treatment is used not only for stroke but also for restenosis because it is effective for treatment of both of these disorders. The point that the

disorders are not the same is noted, however, one is associated with the other and can be the cause and effect for the other, thus, treatment with ancrod is well known to be effective for both.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight or "obvious to try" reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning but not intended to read upon an "obvious to try" standard. However, one of ordinary skill in the art can use reconstructive logical reasoning, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The prior art clearly teaches ancrod, or at least suggests, its use for treating stroke. The claims remain prima facie obvious and the rejection is sustained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware
December 8, 2006

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1287/657